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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/355,705	11/05/1999	HUBERT KOSTER	24743-2303US	6820

7590 01/30/2003

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EXAMINER
SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/355,705	KOSTER ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28,44-51 and 53-57* is/are pending in the application.

4a) Of the above claim(s) *48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28,44-47 and 52-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *24* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. This application contains claims 48-51 drawn to an invention nonelected with traverse in Paper No. 18. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. Acknowledgement is made of applicant having repeated traversal of the restriction requirement. Applicant's arguments have not been considered with effect as applicant's petition of 20 August 2002 has been fully considered and has been **denied** (see Paper No. 22, mailed 23 October 2002). As set forth on Page 3 of the Petition Decision:

> A request for reconsideration or review of this decision must be made by a renewed petition and must be filed within TWO MONTHS of the mailing date of this decision in order to be considered timely.

The two month period in which petitioner could file a renewed petition expired 26 December 2002. With no renewed petition on file, the traversal of the restriction requirement is closed.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-28, 44-47, and 53-57 of this application. The disclosure of the provisional application (priority document) has not been found to provide adequate support for the claimed compositions and related method of making same. In pertinent part, the disclosure of the priority document.

Response to argument

4. At pages 7-8 of the response received 11 October 2002, hereinafter the response, it is asserted that the provisional application does provide support for the claimed invention. Attention is directed to specific lines of pages 2, 4, and 5 of the provisional application.

5. While agreement is reached in that literal support for certain phraseology can be found in the provisional application, such support has not been found to be sufficient to satisfy the written description and enablement requirements of the now-claimed inventions. Accordingly, and in the absence of convincing evidence to the contrary, the provisional application has not been found to adequately support the claimed inventions under 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-28, 44-47, and 53-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-19, 44-47, and 53-56 are drawn to compositions that are comprised of biopolymers which are further defined in dependent claims as being enzymes, nucleic acids (DNA, RNA, analogs or mimetics of DNA or RNA), antibodies, and polypeptides, and that these biopolymers are bound to various supports, be it inorganic, insoluble, magnetic, etc., and that there are various reversible linkages used to

bind the biopolymer to said supports. The aspect of defining a biopolymer as being a nucleic acid (including DNA, RNA, analogs or mimetics of DNA or RNA), as well as being a polypeptide, etc., does not satisfy the written description requirement. *Enzo Biochem Inc. v. Gen-Probe Inc.* (Fed. Cir. 01-0123; April 2002). It is not enough that certain undisclosed embodiments may be obvious when the disclosure is coupled with what was known in the art at the time of filing (*Lockwood*), the specification must provide an adequate written description of the invention and for purposes of examination, the invention is what ever is being claimed. *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (Fed. Cir. 1991).

8. Claim 6 defines the insoluble support as being selected from a group consisting of a flat surface, a microtiter plate, a comb, and a bead." Claim 7 further defines these supports as being "a silicon wafer, glass plate, metal, plastic, film, and composites thereof with pits or wells" which are defined further as comprising inorganic material selected from the group consisting of "silica, Controlled Pore Glass (CPG), plastic, metal, cellulose, agarose and dextran cross-linked with epichlorohydrin" (claim 8). Upon review of the disclosure it is noted that there are but four prophetic examples and of which only example 3 (page 15) is most relevant to the claimed invention. Here it is readily seen that a "bead" of some undisclosed type is contemplated for use. The suggestion in a prophetic example does not reasonably suggest that applicant was in possession of the genus of compositions now being claimed. While literal support may be found in the claims for certain embodiments, the specification does not provide an adequate written description of compositions where all or even some of these requisite elements are combined.

9. The specification does not set forth in sufficient detail the method of claims 20-28 whereby one is to produce the compositions encompassed by claim 1. It is noted that the claimed method requires one to utilize various first and second reversible linkages formed through a trityl derivative, chelate complex, a hydrophobic interaction or a photocleavable functionality" (claim 21). Other claims require that an enzymatic process is used to introduce functionalities into nucleic acids and that this enzymatic process is part of a nucleic acid sequencing reaction. A review of the specification, however, fails to find where such methods are described even in the context of a prophetic example. A review of the specification finds the following examples:

a. Example 1 BAP-his_6 Fusion Protein (page 14)

b. Example 2 Dephosphorylation of DNA Fragments with Solid Phase Bound BAP-his_6 (page 15)

c. Example 3 Detection of LCR Products in Microtiter Filter Plates (pages 15-16)

d. Example 4 Sequence Specific Detection of PCR Fragments (page 16)

The examples and guidance provided is found, at best, to only indirectly suggest or make obvious the claimed methods. It is well settled, however, that in order to satisfy the written description requirements of 35 USC 112, first paragraph, that it is not enough that the invention be rendered obvious by the disclosure. In support of this position attention is directed to the decision in *University of California v. Eli Lilly and Co.* 43 USPQ2d at 1405, citing *Lockwood* 41 USPQ2d at 1966:

> Recently we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

Accordingly, and in the absence of convincing evidence to the contrary, the specification has not been found to provide an adequate written description of the claimed method of producing the claimed compositions.

Response to arguments

10. At page 8, lines 17-21, applicant asserts:

> "[T]he instant claims are not directed to any specific nucleic acids, enzymes or antibodies, but are directed to particular linked arrangements of biopolymers. Therefore there is no need to define what the specific compounds are since any biopolymer is contemplated for use in the claimed compositions."

11. At page 9, paragraph "2," of the response, applicant asserts "that the allegation that alternative embodiments may be obvious in light of the disclosure when combined with the art, is irrelevant because as discussed above, all of the embodiments are fully disclosed in the specification and the specification provides an adequate written description of the claimed subject matter."

12. The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the rejection of claims under 35 USC 112, first paragraph, as it relates to written description. As applicant has indicated in their response, they are seeking to claim not just certain biopolymers that are irreversibly bound to one another "through a linkage formed through a trityl derivative, a chelate complex or a photocleavable functionality," but rather, they are seeking to claim any and all possible such "biopolymers" which, as evidenced by claims 2, 11, 12, encompass any and all possible DNA, RNA, analogs or mimetics of DNA or RNA, and any polypeptide, including but not limited to antibodies, enzymes, receptors and peptides. Accordingly, the nucleic acids and polypeptides and immunoglobulins can be from any life form as well as be created *in vitro* where they have no biological activity or functionality. In short,

applicant is seeking to claim the universe of biopolymers that, at a minimum, are bipartite. Clearly, applicant has not provided an adequate written description of all of the nucleic acids and polypeptides and receptors that exist in the world, yet the claims encompass such. Also, the specification has not been found to provide an adequate written description of those biopolymers that would work over those that have no functionality.

13. While the claims recite the limitation that the reversible linkage between the first and second biopolymer is the result of "a trityl derivative, a chelate complex or a photocleavable functionality," such aspects, for the purpose of examination, have been interpreted as encompassing those steps that could be used in the synthesis of any two biopolymers and that the "reversible linkage" is the normal affinity that one biopolymer has for another, e.g., complementary strands of nucleic acids, the binding of an antibody to an antigen, or the binding of a receptor to a ligand. In view of such an interpretation, the claims are limited to biopolymers that could be simply DNA or proteins. In support of this position, attention is directed to the decision of *Fiers v. Sugano* 25 USPQ2d 1604-5 (CAFC, January 1993) wherein is stated:

> We also reject *Fiers* argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in *Amgen* that conception may occur, *inter alia*, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognize that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute conception of the substance claimed as a process. Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties. . .
> * * * *
> The difficulty that would arise if we were to hold that a conception occurs when one has only an idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before

they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions.

Attention is also directed to the decision of *University of California v. Eli Lilly and Co.* (CA FC, July 1997) 43 USPQ2d 1398 wherein is stated:

> In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.
>
> Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606. (Emphasis added)

In the present case, the claims before the office are considered to be broader than simply claiming cDNA, which as shown above, is not an adequate description of the cDNA, even if it were to be accompanied with the name of the proteins encoded by the cDNAs- a situation that applicant cannot hope to approximate with the instant disclosure. While the third clause of claim

1 could be construed to constitute a product-by-process, the disclosure does not support the position that the genus of claimed biopolymers has been adequately described. In particular, it is not possible to differentiate those biopolymers produced by the claimed method over those that have been produced by another method, not to mention that the one prophetic example does not reasonably suggest that applicant was in possession of the genus of biopolymers claimed. In support of this position attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary. (Emphasis added)
>
> ***
>
> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

Clearly, where as here the claims encompass a vast genus, and with legal precedent as one's guide, the specification does not provide an adequate written description of the claimed genus so as to reasonably suggest that applicant was in possession of the claimed genus of biopolymer composition, in all of its varied manifestations, and as such, the claims are rejected under 35 USC 112, first paragraph.

14. At pages 14-17 of the response traversal of the rejection of claims 6 and 7 is presented wherein attention is directed to page 5, lines 17-26 as providing support for the use of certain insoluble supports.

15. Agreement is reached in that the specification does provide literal support for various insoluble supports. Literal support for limitations of insoluble supports specifically identified in claims 6 and 7 is considered to provide support for possible starting materials that could be used in a method of making the biopolymers. The identification of possible starting materials, however, does not satisfy the written description requirement so to reasonably suggest that applicant was in possession of the claimed genera of compositions.

16. At pages 17-19 of the response argument is advanced that the specification provides an adequate written description of the claimed method of preparing the composition of claim 1. At pages 23-24 of the response applicant also lists publications that have been "cited in the specification." At page 25, last full paragraph, applicant asserts: "Numerous articles cited in the application and attached hereto teach the use of the claimed compositions in DNA sequencing, DNA diagnostics, nucleic acid amplification, Polymerase and Ligase Chain Reactions (PCR, LCR), hybridization experiments and solid phase biochemistry. Therefore the application provides sufficient guidance for one of skill in the art to make and use the full scope of the claimed subject matter."

The above arguments have been fully considered and have not been found persuasive towards the withdrawal of the rejection. While the specification and applicants' remarks may be found to contain citations of other publications, such citations are without effect unless they have been explicitly and appropriately incorporated by reference. Here, applicant has not shown that any of

the documents have been incorporated by reference. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

17. Without proper incorporation by reference, applicant cannot rely upon any of the cited documents as providing either written description for the claimed invention nor can applicant reply upon same for enabling the practice of the claimed methods. Assuming *arguendo*, that the documents had been properly incorporated by reference, the specification is silent as to how these prior art methods are to be modified such that the non-obvious compositions and methods are fully described and enabled. Accordingly, and in the absence of convincing evidence to the contrary the rejection is maintained.

18. Claims 1-28, 44-47, and 53-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Aside from providing an adequate written description of the invention, the specification must also enable the use of the invention. As presently worded, the claims encompass a vast multitude of compositions yet the specification does not set forth in sufficient detail just how one is to differentiate between those embodiments that work and those that will not work. The specification teaches at page 1 that the invention is important to the area of reversibly linking biomolecules where it can be used in "DNA sequencing, DNA diagnostics, nucleic acid amplification, Polymerase and Ligase Chain Reactions (PCR, LCR), hybridization experiments and solid phase biochemistry." At page 3 of the disclosure applicant states that "[b]y combining this reversible concept with other reversible or irreversible linkages, novel biochemical formats including diagnostic assays are possible in which favorable solid phase procedures are coupled with sensitive detection principles." The specification, however, does not teach in sufficient detail just how these multitudinous compositions are to be used in any one of these contemplated methods, much less enable all compositions in all methods. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****

> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

Accordingly, and in the absence of convincing evidence to the contrary, the specification has not been found to enable the use of the claimed compositions.

Response to arguments

19. At pages 19-26 traversal of the enablement rejection of claims 1-28, 44-47, and 53-56 is presented. Applicant argues, *inter alia*, that a proper rejection has not been made and that the level of disclosure provided is sufficient given the level of skill in the art (citations omitted).

20. Agreement is reached in that the specification need not teach each and every possible permutation encompassed by the claims in order to enable same. Agreement is also reached in that some experimentation is permitted so long as the level of experimentation needed on the part of the public is not undue. These points of agreement not withstanding, the specification cannot

be found to enable the use of the claimed compositions when one does not have the requisite starting materials. In order to use the claimed compositions, one must first possess them. As presented above, the specification has not been found to reasonably suggest that applicant was in possession of the genera of biopolymer compositions. Accordingly, one cannot prevail that one is enabled for the use of a composition, be it for treating aging, cancer, mental diseases, etc., when they do not possess it. Note: The claims are not limited to the production of any particular useful biopolymer, but encompass any and all possible biopolymers that have such a reversible linkage, which, as presented above, has been interpreted as encompassing normal binding affinity.

21. Additionally, the disclosure does not teach in sufficient detail how the skilled artisan is to discriminate between the useless biopolymers and those that do have some practical utility. Clearly, not knowing which biopolymer compositions are useful, much less in what method they are to be used and how that method is to be practiced, the skilled artisan is reduced to performing trial and error experimentation. The shifting of this burden from applicant to that of the public would be unfair for the reward of protection being sought by applicant as the amount of experimentation needed to be exerted would not only be great, on the order of many man years, if it could ever be completed, but would also rise to the level of undue experimentation.

22. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained and is also expanded so to encompass newly added claim 57.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. Claims 1, 2, 3, 5, 6-13, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Köster (US Patent 6,225,450 B1) in view of Cook et al. (US Patent 5,543,507).

27. Köster, columns 11-12, discloses the reversible immobilization of biopolymers such as nucleic acids, to any of a variety of solid supports via "a reversible linkage such as a photocleavable bond." Column 14, as well as column 4, discloses a plethora of suitable solid supports, including those whereby the biopolymer would be reversibly bound in an array format.

28. Köster does not disclose the reversible binding of a second biopolymer to that of the first whereby the first and second biopolymers are reversibly linked to one another through a trityl derivative, a chelate complex, or photocleavable functionality.

29. Cook discloses at length a multitude of means whereby a first and second polynucleotides are linked to one another via a trityl derivative, including the use of a heterobifunctional cross-linking agent.

30. It would have been obvious to one of ordinary skill in the art to have incorporated the use of a trityl derivative linking means as disclosed by Cook into the composition of Köster as such would have allowed the artisan the ready capacity to selectively remove a complex from solution as well as a reversible means to then purify said composition fro the solid support as desired, herby saving time, reagents, and associated costs.

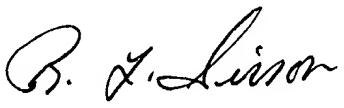
31. In view of the detailed disclosures of Köster and Cook et al., said ordinary artisan would have been motivated to undertake such a combination and would have been motivated to do so as a result of a reasonable expectation of success emanating from the detailed guidance provided.

Conclusion

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

34. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
January 25, 2003